DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

October 12, 2006

Brad Chase
Progressive Health Nutraceuticals, Inc.
3137 W. Central Ave.
PMB #8990
Toledo, OH 43606

Dear Mr. Chase:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.progressivehealth.com and has determined that the products Glucose M1 and Glucose M2 are promoted for conditions that cause these products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Progressive Health Glucose M1

- "Do you want to find out why Glucose-M1 is being used by people experiencing: * * * Type-1 Diabetes * * *Studies have indicated that the ingredients in Glucose-M1 may help maintain normal blood sugar levels for people with Type-1 Diabetes."

- "Glucose M1 Research: * * * Biotin - May help lower blood sugar in diabetics while also improving nervous disorders linked to diabetes. * * *Supplementation with vanadium has been reported to help with diabetes. Animal studies have shown that Vandium can lower blood glucose, decrease cholesterol, and decrease triglycerides. * * *Alpha lipoic acid - Affects insulin as well as blood sugar in type 1 diabetics."

- (Testimonials) "I want to first tell you how excited I am Glucose-M1 worked for me. I replaced my Diabetes medications with your products. As a result, I feel healthier and I now look forward to the next day knowing that my blood sugar has stabilized."

Progressive Health Glucose M2

- "Progressive Health's Type 2 diabetes formula, Glucose M2, drastically improves the quality of care in persons with diabetes, thereby preventing devastating complications from occurring."

- "After being diagnosed with Type 2 diabetes, patients are more susceptible to serious disease conditions. By addressing potential nutrient deficiencies and controlling blood sugar, Glucose M2 works to lessen the risk factors associated with disease onset."

- "[G]lucose M2 can provide you with an effective, alternative option that may regulate blood sugar and reduce susceptibility to diabetes complications."

Furthermore, you offer references on your website for these products. Under 21 CFR 101.93(g)(2)(iv)(C), a citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease.

The following references are implied disease claims:

- "Elamin A, et al. Magnesium and insulin-dependent diabetes mellitus. Diabetes Res Clin Pract. 1990; 10(3):203-9."
- "Brichard SM, et al. The role of vanadium in the management of diabetes. Trends Pharmacol Sci. 1995; 16(8):256-70."
- "Baskaran K, et al. Antidiabetic Effect of a Leaf Extract from Gymnema Sylvestre in Non-insulin-dependent Diabetes Mellitus Patients. J Ethnopharmacol. Oct1990; 30(3):295-300."

Furthermore, these claims are supplemented by the metatags you use to bring consumers to your website. These metatags include "Glucose M1 Helpful For Diabetes Mellitus, Type 1," and "Glucose M2 Helpful For Diabetes Mellitus, Type 2."

Your products are not generally recognized as safe and effective for the above referenced conditions and therefore, they are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

These products are also misbranded within the meaning of Section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. We noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement actions may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.
Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to Quyen Tien, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS-607), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition